

REMARKS

Claims 1, 5-11, and 18 are pending. Among them, Claims 7 and 10 are directed to non-elected species, and are withdrawn from further consideration.

Applicant notes that all previous rejections have been withdrawn in view of Applicant's amendment and arguments submitted with the RCE. However, new obviousness rejections based on newly cited art have been raised. Applicant respectfully requests reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 1, 5, 6, and 18 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Barth (of record) in view of Morgan (U.S. Pat. No. 5,407,953, or "Morgan").

Claims 1, 5, 6, and 18 are also rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Xiao (of record) in view of Morgan.

Claims 1, 5, 6, 8, 9, 11, and 18 are further rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Xiao (of record) in view of Morgan and Hunt (of record).

The gist of these rejections are essentially the same. While the Examiner acknowledges that Barth or Xiao fails to teach treating a patient suffering from primary snoring (*i.e.*, partial nocturnal upper airway obstruction which does not result in hypoxemia), the Examiner argues that "Morgan teaches treating sleep apnea, hypopnea and/or snoring in a human patient (Abstract). Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring (col. 3, ln. 24-29)."

Therefore, the Examiner concludes that "Morgan provides motivation for treating hypopnea and/or snoring with the same medication," and thus "it would have been *prima facie* obvious ... to administer rabeprazole ... and the like, as taught by Barth et al., for the treatment of snoring."

Applicant respectfully disagrees. Applicant submits that this conclusion is based on

incorrect factual inquiries inconsistent with the requirements set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966). In fact, if the logic advanced by the Examiner holds true, one would have to reach the untenable conclusion that *any* treatment method for apnea or hypopnea, such as CPAP (see col. 1, ln. 21-24 of Morgan), can also be a treatment for primary snoring.

As set forth in *Graham v. John Deere Co.*, one of the key factual inquiries based on which obviousness is assessed is “determining the scope and content of the prior art” (emphasis added). If this factual inquiry is improperly conducted, it inevitably leads to an overly broad statement that sets the obviousness determination on the wrong footing.

In the instant case, Morgan states that pilocarpine is effective against glaucoma because it causes “localized therapeutic response of contraction of the smooth muscle of the iris sphincter and of the ciliary muscle” (col. 3, ln. 20-34, emphasis added). Morgan goes on to state that “... we believe that the stimulatory effect of pilocarpine upon the localized smooth muscles of the nasopharynx and hypopharynx results in an alleviation of the nasopharyngeal obstruction that is the apparent cause of obstructive sleep apnea (Modern Medicine, Oct. 30, 1978, pp 26-33.) and snoring.”

Evidently, if Morgan establishes any *nexus* between apnea / hypopnea treatment and primary snoring treatment, it is squarely based on the specific mechanism of action of pilocarpine – causing smooth muscle contraction. Contrary to the assertion in the Office Action, Morgan never establishes any general connection between apnea / hypopnea treatment and primary snoring treatment. In other words, in view of Morgan, one of skill in the art will *not* draw the conclusion that primary snoring can *always or generally* be treated the same way one treats apnea / hypopnea. In fact, Morgan itself doubts whether *all* sleep apnea can be treated the same way, since Morgan suggests pilocarpine may not be effective against central apnea, because the mechanism of central apnea involves interruption of diaphragmatic motion (see col. 3, ln. 31-34; also see Applicant’s explanation in the last response).

An example may help to illustrate the point. One common apnea / hypopnea treatment is prescription drug that helps apnea / hypopnea patients to stay awake during day time, because such

patients frequently exhibit excessive daytime sleepiness. One of skill in the art will surely understand that such prescription drug is not a good option to treat primary snoring, because it does not target the *nexus* established by Morgan – relieving nasopharyngeal obstruction.

Similarly, since neither Barth nor Xiao provides any possible mechanism of action for using the GERD medicines in apnea treatment, one of skill in the art would not know whether these GERD medicines treat apnea / hypopnea through their action on relieving nasopharyngeal obstruction. In fact, since the GERD medicines inhibit acid secretion and reflex in stomach, there is no apparent reason why they may act to relieve nasopharyngeal obstruction. It is quite possible that the GERD medicines, like the anti-sleeping pills, treat apnea / hypopnea through mechanisms entirely independent of relieving nasopharyngeal obstruction. Should that be the case, the limited teaching in Morgan is not helpful, and will not shed any light on the issue of whether the GERD medicines can also be useful in treating primary snoring.

Therefore, a carefully conducted first factual inquiry under *Graham* would lead to the finding that the scope and content of Morgan does not warrant an overly broad conclusion that “hypopnea and snoring can be treated by the same medication,” as the Office Action suggests. In fact, the scope and content of Morgan is quite limited, because not even *all* sleep apnea share the same treatment described in Morgan, let alone all sleep apnea, hypopnea, and primary snoring.

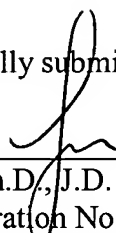
Since there is no teaching that any of the claimed GERD medicines work through a common mechanism / cause for sleep apnea, hypopnea, and primary snoring, one of skill in the art, in view of Barth, Xiao, and Morgan, would have had no motivation to try any of many available apnea / hypopnea treatments on primary snoring patients. Furthermore, one of skill in the art would have had no reasonable expectation that any GERD medicines will work on primary snoring patients in view of Barth, Xiao, and Morgan. Therefore, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the obviousness rejections are respectfully requested.

CONCLUSION

In view of the above amendments, Applicant believes the pending application is in condition for allowance. Applicant believes no fee other than those authorized in the accompanying Fee Transmittal is due with this response. However, if any other fee is due, please charge our Deposit Account No. **18-1945**, from which the undersigned is authorized to draw under Order No. **SOHN-P01-001**.

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Respectfully submitted,

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